K121290

510(k) Summary

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JUN 25 2012

Submitter:	Medtronic Advanced Energy 180 International Drive Portsmouth, NH 03801 USA
Contact Person:	Tara N. Turney, RAC Senior Regulatory Affairs Specialist Phone: 603-742-5445 Fax: 603-742-1488 Email: tara.n.turney@medtronic.com
Date Prepared:	April 27th, 2012
Trade Name:	Aquamantys3 BSC 9.1S
Common Name:	Electrosurgical accessory
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Predicate Device:	Aquamantys3 8.2L Bipolar Sealer with Cutting K111285, cleared September 9th, 2011
Device Description:	The proposed Aquamantys3 BSC 9.1S is a sterile, single-use hemostatic sealing and cutting device. The device employs bipolar radiofrequency (RF) energy and saline for hemostatic sealing and coagulation, and monopolar radio-frequency (RF) energy for cutting. The device is equipped with a dual electrode tip with saline orifices on both sides of the inner electrode at its distal end. Saline and RF energy are supplied to the device from lines on the proximal end of the hand piece. The cassette provides the electrical connection and saline fluid delivery from the Aquamantys3 Generator. The hand piece is equipped with an on-off Transcollation® Sealing Saline button that simultaneously activates both bipolar RF and saline flow for hemostatic sealing using both electrodes. The hand piece is equipped with an on-off Cut button that activates the monopolar RF energy for cutting on a single electrode.
Statement of Intended Use:	The Aquamantys3 BSC 9.1S is a monopolar/bipolar, single use, sterile, disposable device intended for use with the Aquamantys3 Pump Generator. The device delivers bipolar

RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone and monopolar RF energy for cutting of soft tissue. It is intended for, but not limited to, orthopaedic, spine, thoracic, and open abdominal surgery.

The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Summary of Technological Characteristics:

The Aquamantys3 BSC 9.1S applies the same fundamental scientific technology as the existing Medtronic Advanced Energy Bipolar Sealers, with the addition of monopolar RF energy applied without saline, as is seen in the predicate Medtronic Advanced Energy Aquamantys3 8.2L Bipolar Sealer with Cutting (K111285). The device's hand piece is equipped with two activation buttons; the distal yellow button activates monopolar RF energy for cutting, and the proximal blue button activates bipolar RF energy concurrent with saline flow for hemostatic sealing and coagulation. The cord of the Aquamantys3 BSC 9.1S terminates in a cassette that is designed to uniquely insert into the Aquamantys3 Pump Generator, providing simultaneous connection to both RF power and the peristaltic pump. The main differences between the proposed and predicate devices are as follows:

- Tip Configuration
- Hand piece design, including:
  - Ergonomic feel
  - Improved look and design
  - Materials
- Overall length of device
- Malleable shaft

Summary of Non-clinical Data:

The Aquamantys3 BSC 9.1S has undergone bench performance testing to verify and validate the performance features and specifications. The testing included:

- visual,
- static cable pulls,
- dynamic cable pulls,
- static saline tube pulls,
- air leak and flow,
- hipot testing,
- saline flow testing,
- cassette separation,
- shaft deflection/pull,

- electrode pull,
- continuity
- biocompatibility assessment,
- animal tissue testing, and
- electrical safety

Summary of Clinical Data:	Clinical testing was not required to establish substantial equivalence between the proposed and predicate devices.
Conclusion from Data:	Medtronic Advanced Energy has demonstrated that the Aquamantys3 BSC 9.1S is substantially equivalent to the predicate device based upon indications for use, design, test results and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2012

Medtronic Incorporated
% Ms. Tara Turney, RAC
Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

Re: K121290
Trade/Device Name: Aquamantys3 BSC 9.1S
Regulation Number: CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 27, 2012
Received: April 30, 2012

Dear Ms. Turney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

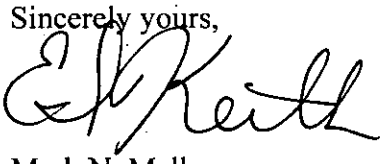
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121290

Indications for Use

510(k) Number (if known):

Device Name: Aquamantys3 BSC 9.1S

Indications for Use: The Aquamantys3 BSC 9.1S is a monopolar/bipolar, single use, sterile, disposable device intended for use with the Aquamantys3 Pump Generator. The device delivers bipolar RF energy concurrent with saline for haemostatic sealing and coagulation of soft tissue and bone and monopolar RF energy for cutting of soft tissue. It is intended for, but not limited to, orthopaedic, spine, thoracic, and open abdominal surgery.

The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark RP Updates for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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